No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association ("AIPLA") is a national bar association of approximately 13,500 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community.[1] AIPLA's members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

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[1] In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter; (ii) no representative of any party to this litigation participated in the authorship of this brief; and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

AIPLA has no stake in any of the parties to this litigation or in the result of this case.

AIPLA has no stake in the parties to this litigation or in the result of this case, other than its interest in the correct and consistent interpretation of the laws affecting intellectual property.[2]

SUMMARY OF ARGUMENT

The Federal Circuit failed to give effect to Congress's recent revisions of the "on sale" provision at 35 U.S.C. §102. Those revisions replaced patent forfeiture for any sale with a prior art effect only for a sale that makes the invention publicly available before a patent application is filed. Congress enacted those revisions as part of the conversion to a "first inventor to file" priority system to bring greater transparency, objectivity, and predictability to the patent system.

Under the 1952 Patent Act, the United States employed a "first to invent" priority system in which the "on sale" doctrine limited an inventor's right to a patent. The "on sale" doctrine required a forfeiture of patent rights if the invention was commercially sold more than a year before the application was filed. Such sales were permitted within a year of filing under a grace period that allowed inventors to determine if their inventions merited patent protection. The potential forfeiture served to

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[2] AIPLA has the consent of the parties to file this amicus brief, pursuant to Supreme Court Rule 37.3(a). Petitioner filed a blanket consent with this Court on August 1, 2018. Respondent consented by counsel via email on August 15, 2018.

incentivize prompt filings of patent applications and to prevent the commercial exploitation of inventions outside of the patent term.

When Congress enacted the America Invents Act ("AIA"), it replaced this "first to invent" system with a "first inventor to file" system to bring U.S. law closer to patent systems around the world. Congress recognized that a first-inventor-to-file system is simpler, more objective, and more transparent than a first-to-invent system.

The first-inventor-to-file system necessarily required revision of the Patent Act, specifically revisions of §102. The purposes of §102, however, remain unchanged: to set out conditions of patentability that ensure the novelty of the claimed invention and its prompt disclosure in a timely-filed application. Congress decided that these purposes are best served by a first-inventor-to-file system. Under that system, a confidential invention date can no longer affect novelty and the incentive for prompt filing is now provided by the risk of losing patent protection to earlier filers.

These revisions to §102 further the AIA's goals of simplicity, objectivity, and transparency. For a sale to be deemed prior art, it must make "the claimed invention" "available to the public." It is not sufficient that the invention was simply the subject of a sale transaction. Patent owners and potential infringers must be able to assess the validity of a patent from publicly available information. With these changes, Congress abandoned the forfeiture model of the former on-sale provision and adopted a model that is based on prior art and that encourages disclosure.

Although the meaning of "available to the public" may need to be developed on a case-by-case basis for different types of inventions, that cannot justify turning a blind eye to Congress's express language. This language requires that, to preclude patentability, a sale must make the "claimed invention" "available to the public." The decision below, however, converts what should be a simple legal issue into a potentially fact-intensive issue in many cases. This would increase the time and expense required for discovery, motion practice, trial, and appellate review of this subjective issue of forfeiture, directly contrary to Congressional intent.

ARGUMENT

I. The Federal Circuit Failed to Enforce the Statutory Requirement That an Inventor's Sale Must Make the "Claimed Invention" Public for Prior Art Effect.

The question presented is: "Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention?" AIPLA respectfully submits that the answer is "no."

This Court should reverse the decision below because the Federal Circuit focused too narrowly on the words "on sale" rather than construing the entire provision at issue, 35 U.S.C. §102. Congress expressly revised §102(a) to require that a public use or sale

make the "claimed invention" publicly available to qualify as prior art. This feature is central to the AIA's purposes of making U.S. law more efficient and predictable, and of harmonizing it with international standards for prior art.

A. Pre-AIA §102 Included "Loss of Right" Forfeiture Provisions.

Prior to Congress's adoption of the AIA in 2011, §102 of the Patent Act set out certain conditions of patentability. It ensured the novelty of the claimed invention based on its date of invention (§102(a)), and encouraged prompt disclosure of the invention by setting out certain impermissible activities before the patent application is filed (§102(b)). Failure to satisfy the novelty requirement resulted in patent invalidity for anticipation. Failure to satisfy the prompt filing requirement resulted in forfeiture of patent rights, regardless of how novel the invention may have been.[3]

Pre-AIA §102, in pertinent part, reads as follows:

> **§102. Conditions for patentability; novelty and loss of right to patent**

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[3] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998) ("In *Andrews v. Hovey*, 123 U.S. 267, 274 ... (1887), we noted that the purpose of [§102(b)] was 'to fix a period of limitation which should be certain'; it required the inventor to make sure that a patent application was filed 'within two years from the completion of his invention,' *ibid.*"). *See also Application of Foster*, 343 F.2d 980, 987-88 (C.C.P.A. 1965) ("[Section 102(b)] presents a sort of statute of limitations, formerly two years, now one year, within which an inventor, even though he has made a patentable invention, must act on penalty of loss of his right to patent.").

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or....

35 U.S.C. §102 (1994). As indicated in its title, the pre-AIA version of §102 imposed two conditions on patentability: "novelty" and "loss of right."

The distinction between novelty (which turned on the date of invention) and loss of right (which turned on the filing date) was well-recognized in the law.[4] Professor Chisum's leading treatise explained as follows:

> The novelty provisions should not be confused with the "statutory bar" or "loss of right" provisions in Section 102.

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[4] Pre-AIA §§102(e) and (g) were also novelty provisions that ensured a patent would only be awarded to the first person to invent an invention. Pre-AIA §102(f) denied the applicant a patent if "he did not himself invent the subject matter sought to be patented."

> Sections 102(b), 102(c)[5] and 102(d)[6] all relate to events and acts by the inventor or by other persons prior to the date when the inventor applies for a patent. The point of a statutory bar is that an inventor of a product or process that may have been new and patentable at the time of invention can lose the right to obtain a patent by tardiness in applying for a patent.

1 Donald S. Chisum, *Chisum on Patents*, §3.02, at 3-9 (2012) ("*Chisum*"). An inventor may have come up with something new, but still lose, be barred from, or forfeit the right to a patent if he or she did not pursue a patent application within the prescribed time. *See, e.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) ("an inventor loses his right to a patent if he puts his invention into public use before filing a patent application") (citing *Pennock v. Dialogue*, 2 Pet. 1, 24, 7 L.Ed. 327 (1829)). Sections 102(b), (c) and (d) focused on the inventor's actions and/or inaction, not the novelty of the claimed invention. *See also Chisum*, §6.01, at 6-4 ("The general purpose behind all the bars is to require inventors to assert with due diligence

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[5] "A person shall be entitled to a patent unless – (c) he has abandoned the invention." 35 U.S.C. §102(c) (1994).

[6] "A person shall be entitled to a patent unless – (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States." 35 U.S.C. §102(d) (1994).

their right to a patent through the filing and prosecution of a patent application.").

In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), this Court explained:

> Sections 102(a) and (b) operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public. They express a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use.

Id. at 148. Sections 102(a) and (b) were part of the 1952 Patent Act's "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.* at 146.

This Court has recognized that pre-AIA §102(b), and the on sale bar in particular, required prompt filing of patent applications. This prevented inventors from commercially exploiting their inventions for longer than the prescribed patent term. In *Pfaff*, the Court stated that "§102 of the Patent Act serves as a limiting provision ... confining the duration of the monopoly to the statutory term." 525 U.S. at 64. Section 102(b) provided the inventor a one-year grace period to determine if the invention was worth the cost of patenting. Thereafter the inventor had to file a

patent application to ensure he or she could not exploit the invention commercially for more than the grace period plus the statutory term. *E.g., General Electric Co. v. U.S.*, 654 F.2d 55, 61 (Ct. Cl. 1981).

B. The AIA's "First Inventor to File" System Replaced Forfeiture as the Incentive for Prompt Filing.

Perhaps the most significant change to U.S. patent law made by the AIA was the replacement of the "first to invent" system with a "first inventor to file" system. H.R. REP. No. 112-98, at 40 (2011). ("The 'America Invents Act' creates a new 'first-inventor-to-file' system."). This change brings U.S. patent law closer to that of every other industrialized nation, each of which uses a first-to-file system. *Id.*

As noted above, one of the policies behind the various statutory bars, including the on-sale bar, was to incentivize the inventor to file diligently a patent application or risk losing the right to a patent. The AIA first-inventor-to-file system expressly replaces this loss-of-right incentive. Congress "provide[d] ample incentive for an inventor to enter the patent system promptly" in the AIA "[b]y adopting the first-to-file system." Cong. Rec. S1371 (March 8, 2011) (1st col.) (remarks of Sen. Kyl).[7] AIA §102(a)(1) preserves the incentive to file promptly by including in the prior art those acts that had resulted in forfeiture under the pre-AIA law. A sale before the prescribed date which makes the claimed invention "available to the public" does not forfeit the patent. It does, however, create a

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[7] All citations to the Congressional Record in this brief are to volume 157 of the daily edition.

disclosure which is given prior art treatment for determining anticipation under §102 or obviousness under §103.

The "available to the public" requirement permits an applicant to make a confidential sale and avoid the on-sale limitation. This possibility, however, reflects a policy decision Congress made to favor disclosure. By preserving the inventor's right to a patent, notwithstanding a confidential sale, Congress chose to provide a continuing incentive for the inventor to make the subject matter of the invention publicly available by filing a timely patent application.

Prompt and complete disclosure of inventions in patent applications is necessary to the bargain between the inventor, who receives exclusive rights in the invention, and the government acting on behalf of the public. The Court recognized in *Bonito Boats*:

> The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. "[The inventor] may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon expiration of that period, the knowledge of the

> invention inures to the people, who are thus enabled without restriction to practice it and profit by its use."

489 U.S. at 150-51 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–187 (1933)).

Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946), is the seminal decision on the effect of a secret sale on patent validity under the pre-AIA §102. In that case, the issue was the secret use of a process before the grace period and the sale of the unpatented products of that process. The on-sale bar applied because the patent owner was benefitting simultaneously from both trade secret and patent protection. Judge Hand wrote: "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; ***he must content himself with either secrecy, or legal monopoly.***" *Id.* at 520 (emphasis added).[8]

When enacting the AIA, Congress determined that forfeiting patent rights is more harmful than allowing confidential sales but retaining an incentive to disclose an invention in a promptly filed patent application. Under pre-AIA §102, individual and/or unsophisticated inventors have forfeited their rights to patents because of limited and private uses that did

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[8] In response to comments that the PTO should preserve the rule of *Metallizing Engineering* and related doctrines despite the AIA, the PTO wrote "some of the purposes ascribed to these doctrines in case law appear to be ill-suited to or inconsistent with the AIA." 78 Fed. Reg. 11059, 11075 (3d col.).

not disclose the claimed invention to the public.[9] "The only effect of rulings like these is to create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the [pre-AIA section 102(b)]." Cong. Rec. S1371 (1st col.) (remarks of Sen. Kyl).[10]

The enactment of the AIA moves the United States closer to the rest of the industrialized world in having a system that awards patents to the first inventor to file an application. Under that standard, there is no reason or need to bar patents after secret commercial use:

> There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public. And the current on-sale bar [of pre-AIA §102(b)] imposes penalties not demanded by any legitimate public interest. There is no reason to fear "commercialization" that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.

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[9] As examples, the Congressional Record cites *Egbert v. Lippman*, 104 U.S. 333 (1881) (corset spring inherently hidden from view and given to only one woman held to be "in public use"); *Beachcombers Int'l, Inc. v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1159-60 (Fed. Cir. 1994) (improved kaleidoscope "in public use" because shown to guests at private party); and, *JumpSport, Inc. v. Jumpking, Inc.*, 191 Fed. Appx. 926 (Fed. Cir. 2006). *See* Cong. Rec. S1371 (1st & 2d col.).

[10] *See also* cases discussed at note 20 *infra*.

Cong. Rec. S1371 (March 8, 2011) (1st col.) (remarks of Sen. Kyl discussing §102 of S. 23). The first-inventor-to-file system provides a strong incentive to file promptly and to disclose the invention to the public. Every day an inventor delays filing a patent application, even if it adds another day's profit from the invention, risks losing twenty years of patent protection to another inventor who files first.

This Court has already determined that "the nature and degree of state [trade secret] protection did not conflict with the federal policies of encouragement of patentable invention and the prompt disclosure of such innovations." *Bonito Boats*, 489 U.S. at 155. The Court recognized that "'[t]rade secret law provides far weaker protection in many respects than the patent law.'" *Id.* (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489-90 (1974)). The Court elaborated:

> The public at large remained free to discover and exploit the trade secret through reverse engineering of products in the public domain or by independent creation. Thus, the possibility that trade secret protection would divert inventors from the creative effort necessary to satisfy the rigorous demands of patent protection was remote indeed.

Bonito Boats, 489 U.S. at 155 (citing *Kewanee Oil*, 416 U.S. at 490).

C. The Federal Circuit Erroneously Interpreted AIA §102.

Although the words "on sale" are the same in pre-AIA §102(b) and AIA §102(a)(1), the context in which these words appear differs fundamentally. It was error for the Federal Circuit to ignore the entirety of the changes to §102(a)(1) that were enacted by the AIA in adopting the new "first inventor to file" patent system. Courts have a "duty to construe statutes, not isolated provisions." *Graham County Water and Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 290 (2010) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 568 (1995)). The entirety of the revised §102, particularly in the context of Congress's overall policy decision in enacting the AIA, requires that all forms of prior art be "available to the public."

1. The Plain Language of AIA §102(a)(1) Imposes a Requirement of Public Availability on Prior Art.

AIA §102(a)(1) provides:

> (a) Novelty; Prior Art.—A person shall be entitled to a patent *unless*—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention....

35 U.S.C. §102(a)(1) (2012) (emphasis added). Inventors are entitled to patents "unless" they cannot overcome the prior art, making the identification of prior art fundamental to the patent system.

The AIA struck pre-AIA §102(a) entirely. The following redline reveals the changes made by the AIA to the pre-AIA §102(b):

> (a) Novelty; Prior Art. ~~Conditions for patentability; novelty and loss of right to patent~~ A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, ~~or~~ described in a printed publication, ~~in this or a foreign country~~ or in public use, ~~or~~ on sale, ~~in this country,~~ or otherwise available to the public before the effective filing date of the claimed invention; ~~more than one year prior to the date of the application for patent in the United States~~....

35 U.S.C. §102(a)(1) (2012). Critical differences between the pre- and post-AIA versions include:

> (1) the title is changed to strike "loss of right to patent" and to insert "Prior Art," reflecting the provision's focus on prior art rather than forfeiture;
>
> (2) "claimed" now modifies "invention";
>
> (3) "in this country" no longer appears after "in public use or on sale";
>
> (4) the modifier "or otherwise available to the public" was added following the list of patent-defeating prior art; and,
>
> (5) "more than one year prior to the date of the application for patent in the United States" was changed to "before

> the effective filing date of the claimed invention."[11]

The decision below failed to give full effect to these revisions, despite the express language of §102(a)(1).

The AIA introduces definitions for (1) "claimed invention" as "the subject matter defined by a claim in a patent..." (35 U.S.C. §100(j)) and (2) "effective filing date" of a given claimed invention (35 U.S.C. §100(i)).[12] The subject matter is defined by ***all*** of the claim's limitations. The statute places the "claimed invention" in the prior art only if it was on sale "or otherwise available to the public" before the "effective filing date of the claimed invention." 35 U.S.C. §102(a)(1). The term "otherwise" means "in a different way or manner." *Merriam-Webster's Collegiate Dictionary*, at 823 (10th Ed. 1998). Thus, the "claimed invention" is prior art only *where it is made available to the public, by sale, use, or otherwise.*

By not requiring all of the limitations of the "claimed invention" to be "available to the public," the decision below effectively removed both terms—

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[11] The panel decision below reveals a misunderstanding of the AIA by referring in several places to the patent's "critical date." Pet. App. at 19a, 20a, and 25a-27a. "Critical date" refers to the date more than one year before the filing of a patent application under the 1952 Act to determine the grace period for such filings. *Monon Corp. v. Stoughton Trailers, Inc*., 239 F.3d 1253, 1257 (Fed. Cir. 2001). The relevant term under §102(a)(1), however, is "effective filing date," defined at 35 U.S.C. §100(i) as "the actual filing date of the patent or the application for the patent containing a claim to the invention" or "the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority...."

[12] *See* note 11 *supra* for the AIA's definition of "effective filing date."

"claimed"[13] and "otherwise"—from the statute. *E.g.*, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.").

The changes to the title of §102 confirm the imposition of the public availability requirement on all categories of prior art. The words "loss of right to patent" were removed from the title. Only "Novelty; Prior Art" remain. The "public use" and "on sale" provisions of pre-AIA §102(b) were loss of right or forfeiture provisions, not prior art or novelty provisions. The title changes reflect that "in public use" and "on sale" are now categories of prior art.

Under the AIA, Congress created an incentive to file promptly by providing that only the first inventor to file receives a patent. As reflected in its title, AIA §102(a)(1) identifies certain actions and documents as prior art and does not include any loss of right provision. Imposing a public availability requirement on sales is consistent with the fact that qualifying sales are now part of the prior art. Thus, §102(a)(1) should be construed, consistent with its plain language, to require that all the listed forms of prior art must be "available to the public."

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[13] The Federal Circuit decision acknowledges that at least one element of the claimed invention, the dosage, was not disclosed to the public before the effective filing date of the patent. Pet. App. at 24a.

2. Congress Intended to Change the Law Developed under Pre-AIA Court Decisions.

The Federal Circuit relied on pre-AIA law to construe the AIA's §102(a)(1) because it felt Congress's intent to change the law was not sufficiently clear. Appendix to Petition for Certiorari ("Pet. App.") at 11a (citing *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). Congress's intent to impose a public availability standard for prior art is clear from the express statutory language "or otherwise available to the public."

The changes to §102(a)(1) are analogous to the changes to 28 U.S.C. §1367 which the Court considered in *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546 (2005). In *Exxon*, the Court addressed whether an amendment to §1367 overruled *Zahn v. Int'l Paper Co.*, 414 U.S. 291 (1973). Responding to an argument that the Court should consider other canons of construction because the amended statute was ambiguous, the Court held: "We can reject this argument at the very outset simply because §1367 is not ambiguous." *Id.* at 567. Earlier in the opinion, the Court stated:

> No sound canon of interpretation requires Congress to speak with extraordinary clarity in order to modify the rules of federal jurisdiction within appropriate constitutional bounds. Ordinary principles of statutory construction apply. In order to determine the scope of supplemental jurisdiction authorized by §1367, then, we must

> examine the statute's text in light of context, structure, and related statutory provisions.

Id. at 558. AIA §102(a)(1) is likewise unambiguous when it requires that prior art must be "available to the public." Congress is no more required to speak with "extraordinary clarity" when amending patent law than it was when amending §1367.

The decision below also erred by construing §102(a)(1) according to pre-AIA case law because, as illustrated in detail above, post-AIA §102(a)(1) includes at least five major changes to pre-AIA §102(b). Congress is presumed to adopt the prior interpretation of a statute only "when it re-enacts a statute without change." *Lorilland v. Pons*, 434 U.S. 575, 580 (1978). Congress fundamentally changed §102 and cannot be presumed to have adopted any prior interpretations.[14]

Section 102 was not reenacted without change. In particular, the subject of the on-sale condition was changed from "the invention" to "the claimed invention." This deliberate change by Congress requires not simply the public availability of the invention but the public disclosure of the invention as claimed, which in this case would have to include the claimed dosage under Helsinn's patent.[15]

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[14] This Court's decision in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), continues to govern the first two requirements for an invention to be "on sale," namely, (1) a commercial offer for sale of an invention that is (2) ready for patenting. *Id.* at 67. The public availability requirement was not at issue in *Pfaff*.

[15] The Federal Circuit responded to this issue by citing its 1989 decision that the details of an invention need not be disclosed for

The decision below also relied on *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829), for the proposition that a sale can be invalidating even though it withholds "from 'the public the secrets of [the] invention.'" Pet. App. at 40a. But *Pennock* also does not support this proposition. In *Pennock*, the inventors (Pennock and Sellers) disclosed their invention to a third-party (Jenkins) without imposing any confidentiality obligation, making it publicly available. 27 U.S. at 3. In the language of the Patent Act at the time, the invention was "known or used before the application" and thus a patent was barred. Ch. 11, §1, 1 Stat. 319. The portion of the *Pennock* opinion quoted by the panel is a series of hypothetical statements, introduced by "if," that do not constitute a holding of the case.

3. AIA §102(b) Confirms That Public Uses and Sales Now Create Prior Art, Not Forfeiture Events.

AIA §102(b) provides "exceptions" to the prior art consequences identified in §102(a). Section 102(b) confirms that §102(a) now deals only with the prior art disclosures, and that any loss of right or forfeiture provisions have been eliminated from the statute. Section 102(b) reads:

(b) Exceptions.—

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the on-sale bar to apply. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989). The response is inadequate because it fails to address the law as changed by the new statute. The response is also *dictum* since the *RCA* court found a sufficient technical description of the invention albeit in words different from the claim language. *Id.*

> (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention ***shall not be prior art*** to the claimed invention under subsection (a)(1) if....

35 U.S.C. §102(b) (2012) (emphasis added). The plain language creates an exception to prior art, not an exception to the former loss-of-right provisions.

The legislative history of AIA §102(b) confirms the plain language reading that public availability is required for sales to have any prior art effect. Explaining the one-year grace period of post-AIA §102(b), Senator Leahy (one of the AIA's two namesakes) stated:

> We intend that if an inventor's actions are such as to constitute prior art under subsection 102(a), then those actions ***necessarily*** trigger subsection 102(b)'s protections for the inventor and, what would otherwise have been section 102(a) prior art, would be excluded as prior art by the grace period provided by subsection 102(b).

Cong. Rec. S1496 (March 9, 2011) (2d col.) (emphasis added). Immediately afterwards, Senator Hatch stated:

> The Senator from Vermont is correct. For the purposes of grace-period protection, the legislation intends

> parallelism between the treatment of an inventor's actions under subsection 102(a) that might create prior art and the treatment of those actions that negate any prior-art effect under subsection 102(b).

Id. (3d col.).

Senators Hatch and Leahy's comments were echoed in the House by Representatives Bass and Smith (the other of the AIA's namesakes) as follows:

> Mr. SMITH of Texas. I want to respond to the gentleman from New Hampshire and say that one key issue for clarification is the interplay between actions under section 102(a) and actions under section 102(b). ***We intend for there to be an identity between 102(a) and 102(b). If an inventor's action is such that it triggers one of the bars under 102(a), then it inherently triggers the grace period subsection 102(b).***
>
> Mr. BASS of New Hampshire. I believe that the chairman is correct. ***The legislation intends parallelism between the treatment of an inventor's action under 102(a) and 102(b).*** In this way, small inventors and others will not accidentally stumble into a bar by their pre-filing actions.

Cong. Rec. H4429 (June 22, 2011) (1st col.) (emphasis added). Congress's express intent was for post-AIA §§102(a) and 102(b) to function together as a recitation of prior art and corresponding exceptions. Thus, a non-public sale cannot constitute prior art under AIA §102(a)(1) because a non-public sale is not a disclosure and by definition falls outside the grace period of AIA §102(b).

The word "disclosed" in §102(b)(1)(B) means "publicly disclosed." The plain meaning of the word is clear enough. Congressional intent confirms this:

> I would have thought that the meaning of the word would be clear: a disclosure is something that makes the invention available to the public - the same test applied by section 102(a) to define the scope of the prior art. And "available to the public" means the same thing that "publicly accessible" does in the context of a publication.

Cong. Rec. S1042 (March 1, 2011) (1st col.) (remarks of Sen. Kyl). In short, there is no distinction between "disclosed" in §102(b)(1)(A) and "publicly disclosed" in §102(b)(1)(B). Section 102(b) does not alter the plain language of §102(a) imposing a public availability requirement on any and all forms of prior art in that section.

II. The Legislative History, USPTO Interpretation, and Public Policy Each Provide That "On Sale" Must Make the "Claimed Invention" Publicly Available for Prior Art Treatment.

A. The Legislative History Supports the Public Availability Requirement.

Section 102(a)(1) requires that, to qualify as prior art, the "claimed invention" must be "available to the public." Even if the language of §102(a)(1) were ambiguous, however, the legislative history unambiguously imposes a public availability standard on prior art. The House Report on the AIA explains that "[p]rior art will be measured from the filing date of the application and will typically include all art that ***publicly exists*** prior to the filing date, other than disclosures by the inventor within 1 year of filing." H.R. REP. NO. 112-98, at 42 (2011) (emphasis added). The House Report continues that "the phrase 'available to the public' [was] added to clarify the broad scope of relevant prior art, ***as well as to emphasize the fact that it must be publicly accessible.***" *Id.* at 42-43 (emphasis added). This legislative history confirms the statutory language that all prior art, including sales, must make the invention available to the public. The decision below ignores this Report.

Other portions of the House Report confirm that Congress intended to impose a public availability requirement on prior art, although less explicitly than the portions quoted in the prior paragraph. The report states "[t]he Act ... simplifies how prior art is

determined, provides more certainty, and reduces the cost associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42 (2011). *See also id.* at 40 (the "legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). The AIA §102(a)(1) requirement for claimed inventions to be publicly available to qualify as prior art simplifies how prior art is determined and the decision to seek patent protection because it eliminates the need to scour private records and conduct interviews in search of a disqualifying sale or use. The public availability requirement also lessens discovery in litigation by eliminating an otherwise fact-intensive inquiry into whether the claimed invention was subject to any potentially invalidating uses or sales and whether any such use or sale was experimental.

Proposed versions of §102(a)(1) in draft bills from 2005 through 2008 removed the "public use" and "on sale" terms and included a general "publicly known" clause. This history does not show, however, that by restoring "public use" and "on sale" in the final version Congress intended to retain prior "on sale" law unchanged. Rather, Congress retained public uses and sales as categories of prior art and expressly imposed the requirement that they be publicly available to qualify as prior art.

B. The PTO's Reasonable Interpretation Supports the Public Availability Requirement.

The PTO participated in the AIA legislative process and discussed its implementation with Congress.[16] After the AIA's passage, the PTO conducted an extensive notice and comment procedure to prepare guidance for its personnel on how to administer the statute. 78 Fed. Reg. 11059, at 11060. The PTO concluded that "otherwise available to the public" is a "catch-all" provision that focuses on whether the disclosure was "available to the public" rather than whether it falls within another prior art category defined by the statute. *Id.* at 11075 (2d col.). The PTO agrees that the plain language of §102(a)(1) imposes a public availability requirement on public uses and sales:

> The starting point for construction of a statute is the language of the statute itself.... AIA 35 U.S.C. 102(a)(1) contains the additional residual clause "or otherwise available to the public." Residual clauses such as "or otherwise" or "or other" are generally viewed as modifying the preceding phrase or phrases. Therefore, the Office views the "or otherwise available to the public"

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[16] *See, e.g.*, March 30, 2011 hearing: https://judiciary.house.gov/hearing/hearing-on-h-r-1249-the-america-invents-act-0/ (last visited Aug. 16, 2018); May 16, 2012 hearing: https://judiciary.house.gov/hearing/hearing-on-implementation-of-the-leahy-smith-america-invents-act-0/ (last visited Aug. 16, 2018).

> residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art.

Id. at 11062 (2d col; footnotes omitted).

Under the PTO's guidelines, the public availability requirement applies to all documents and activities itemized in §102(a)(1):

> The Office's interpretation of AIA 35 U.S.C. 102(a)(1) also ensures that the AIA grace period can extend to all of the documents and activities enumerated in AIA 35 U.S.C. 102(a)(1) that would otherwise defeat patentability. In addition, this interpretation avoids the very odd potential result that the applicant who had made his invention accessible to the public for up to a year before filing an application could still obtain a patent, but the inventor who merely used his invention in secret one day before he filed an application could not obtain a patent.[17] Finally, the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of

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[17] This "very odd potential result" would come about because of the exceptions to prior art in AIA §102(b) discussed above. If §102(a) did not impose a public availability requirement, then a secret use would create prior art which could defeat a patent. AIA §102(b) creates an exception to prior art for disclosures by the inventor up to one year before the filing date. A secret use does not fall within §102(b)'s exceptions, however, because they require disclosure.

> the AIA during the congressional deliberations on the measure.

Id. (footnotes omitted); *see also* Brief for the United States as *Amicus Curiae* at 5, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), No. 16-1284 ("Brief of USA").

At a minimum, the PTO's interpretation is consistent with the statutory language and legislative history. It also resolves conflicting policies between simplifying the determination of prior art to make the patent system more efficient and objective, providing an incentive to file patent applications promptly, and avoiding exploitation of inventions beyond the statutory term for a patent. Thus, it is eminently reasonable and the Court can rely on it under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), which held:

> We consider that the rulings, interpretations, and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those

> factors which give it power to persuade, if lacking power to control.

Id. at 140.

C. The "Public Availability" Requirement Advances Congress's Policy Objectives

The "public availability" requirement is consistent with Congress's decision to transform the U.S. patent system "from one of non-transparency, subjectivity, unpredictability and excessive complexity, to one that will operate with near-complete transparency, objectiveness, predictability and simplicity...." Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 9 (2012) ("Armitage"). Determining the date of invention under the former "first to invent" system was a fact sensitive endeavor involving determinations of dates of conception and reduction to practice and of the inventor's diligence. *See, e.g., Pfaff*, 525 U.S. at 61 (citing 35 U.S.C. §102(g)). The AIA eliminated fact-sensitive, discovery-intensive, and subjective elements such as the "best mode" defense from pre-AIA §112[18] and "deceptive intention" from pre-AIA §§116, 251, 253, 256, and 288. The AIA also added new §257 on supplemental examination to address the fact-sensitive, discovery-

[18] *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) (whether best mode existed is subjective based on "what the inventor actually believed at the time the application was filed").

intensive, and subjective inequitable conduct defense.[19]

Under pre-AIA §102(b), interested parties cannot readily determine whether a patent will be subject to a public use or on-sale invalidity defense. Prior uses or sales, if any, must be investigated but the relevant evidence may be private. In addition, an inventor must make a judgment as to whether the invention is "ready for patenting" or whether further experimentation is required. *See Pfaff*, 525 U.S. at 64 ("The law has long recognized the distinction between inventions put to experimental use and products sold commercially."). These questions can only be answered after completing extensive document review and multiple interviews or depositions.

The experimental use exception to the on-sale bar is particularly fact sensitive, requiring consideration of the following factors:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing[,] . . . (10) whether the invention reasonably requires evaluation under actual conditions of

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[19] *See* Armitage, 40 AIPLA Q.J. at 9.

> use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Allen Eng'g, Inc. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002). When the on-sale bar is at issue, the parties naturally will seek documents and testimony bearing on all these factors. In patent prosecution or transactions, this additional due diligence adds cost and risk and, in litigation, the discovery often triggers disputes that require court intervention, extends the length of any trial, and creates a voluminous record for appeal.

The Federal Circuit's failure to recognize that the public availability requirement applies to claimed inventions undermines a critical purpose of the AIA: to make the patent system simpler and more predictable. By reducing the effort to achieve due diligence or discovery to determine if a sale is prior art under §102(a)(1), Congress created the certainty required for parties investing in patent applications, pursuing licenses or acquisitions, and evaluating patent litigation. In addressing its concern for costs and wasted resources, Congress balanced the need for limiting exclusive rights in a free market against the importance of the patent system to U.S. innovation. The Federal Circuit decision interferes with this policy balance uniquely committed to the legislature, not to the judiciary.

The Federal Circuit decision also interferes with Congress's attempt to reduce the number of fact

issues that dominated pre-AIA case law. The Federal Circuit's opinion states: (1) "the AIA did not change the statutory meaning of 'on sale' ***in the circumstances involved here***," Pet. App. at 20a (emphasis added); and (2) "[w]e do not find that distribution agreements will always be invalidating under §102(b) [*sic* – 102(a)]. We simply find that this particular Supply and Purchase Agreement is." Pet. App. at 43a. The opinion concurring in the denial of rehearing *en banc* also portrayed the decision as fact-specific. Pet. App. at 5a. Thus, the decision below will continue to require substantial time and expense for investigation, discovery, motion practice, trial, and appeal to define the specific sales arrangements that do or do not constitute prior art. This result is contrary to the Congressional intent "to reduce the costs associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42.

Moreover, old "public use" and "on sale" law led to many outcomes that defied logic and no longer serve any policy objective under the AIA.[20] As one commentator wrote:

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[20] *See, e.g., Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357-1358 (Fed. Cir. 2001) (refusing to recognize a "supplier" exception to the on-sale bar); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (finding an inventor's own secret commercial use before the grace period may be a public use barring patentability); *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1454 (Fed. Cir. 1997) (refusing to create an exception to the on-sale bar for sales before the grace period that result from a misappropriation of the invention by a third party); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946) (applying the on-sale bar to sales before the grace period of unpatented products made by the secret use of the patented

> It is one of the ironies of the pre-AIA patent law that §102(a)'s invalidating "use" must make an invention accessible to the public, while §102(b)'s "public use" can include private uses that are not accessible to the public. *See Woodland Trust*, 148 F.3d at 1370; *Trading Tech. Int'l, Inc. v. eSpeed, Inc.*, 507 F. Supp. 2d 883, 893 (N.D. Ill. 2007), *aff'd*, 595 F.3d 1340 (Fed. Cir. 2010) (finding that the secret commercial use of an inventor's own invention may constitute public use).

Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012). If the Court retains the pre-AIA construction of "on sale," it will extend the uncertainty and oddity of the old interpretation. Further, it will undermine Congress's objectives to make the outcome of patent prosecution and litigation more predictable and efficient.

In addition to making the patent system more efficient, objective, and predictable, other policy considerations support excluding secret sales from the prior art under §102(a)(1). Congress also imposed this public availability requirement on prior art to protect U.S. businesses from having their inventions

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process); *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (finding the sale of "burglar-proof" safes to be a public use despite testimony that technology was completely concealed within the safe).

stolen or patents invalidated by unscrupulous foreign competitors. Senator Kyl stated:

> Finally, ***validating prior art will depend on publicly accessible information***, not private activities that take place, for example, in a foreign land. As a result, it will be impossible for a third party who derived the invention from a U.S. inventor's public disclosure or patent application to steal the invention or sabotage the U.S. inventor's patent.

Cong. Rec. S5320 (Sept. 6, 2011) (3d col.) (emphasis added). To allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions, contrary to Congress's expressed intent. Congress intended to protect U.S. inventors from this risk by confirming that a sale before the effective filing date must make the "claimed invention" "available to the public" to qualify as invalidating prior art.

Congress also removed secret sales as a forfeiture of patent rights to achieve greater substantive harmonization of patent laws among the U.S., Europe, Japan, and other countries. AIPLA is not aware of any foreign country that uses a first-to-file system and also includes secret sales as a basis for a loss of right to a patent.[21] The House Report on the

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[21] The Government made a similar assertion in its amicus brief below. Brief of USA at 10. The fact no other country considers secret sales to be prior art confirms that the adoption of a first-inventor-to-file system provides a sufficient policy incentive to ensure early disclosure. It also mitigates any concern that

AIA cites "the value of harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world for the benefit of U.S. patent holders" as one of the motivations for the bill. H.R. REP. NO. 112-98, at 39. Conversely, maintaining secret sales as a basis for losing the right to a patent would detract from Congress's goal of further harmonizing U.S. patent law with that of other major industrialized nations.

III. CONCLUSION

The Court should reverse the decision below and uphold the AIA's express requirement that sales of the "claimed invention" must be "available to the public" to qualify as prior art.

Respectfully submitted,

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companies may keep their process inventions secret for years and then file patent applications at the last minute.